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**UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY**

SUPERNUS PHARMACEUTICALS, INC.,

Plaintiff,

v.

ACTAVIS INC., et al.,

Defendants.

Civil Action No. 14-6102 (SDW)(LDW)

(Filed Electronically)

Oral Argument Requested

SUPERNUS PHARMACEUTICALS, INC.,

Plaintiff,

v.

**ZYDUS PHARMACEUTICALS (USA)
INC., et al.,**

Defendants.

Civil Action No. 14-7272 (SDW)(LDW)

(Filed Electronically)

Oral Argument Requested

SUPERNUS'S RESPONDING CLAIM CONSTRUCTION BRIEF

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TABLE OF ABBREVIATIONS

“Byrn Decl.”	The opening declaration of Dr. Stephen R. Byrn, which was filed with Supernus’s opening brief. (C.A. 14-6102, Dkt. No. 88-25; C.A. 14-7272, Dkt. No. 74-25.) Exhibits to the Byrn Declaration are referenced as “Byrn Decl. Ex. ____.”
“Byrn Resp.”	The responding declaration of Dr. Byrn, which is filed concurrently herewith. Exhibits to the Byrn Responding Declaration are referenced as “Byrn Resp. Ex. ____.”
“Defs. Br. ____”	Defendants’ Opening Claim Construction Brief. (C.A. 14-6102, Dkt. No. 91; C.A. 14-7272, Dkt. No. 77.)
“Ex. ____”	Exhibits to the Declaration of Richard F. Kurz, which was filed with Supernus’s Opening Claim Construction Brief. (C.A. 14-6102, Dkt. No. 88-1; C.A. 14-7272, Dkt. No. 74-1.)
“Thakker Decl.”	The opening declaration of Dr. Dhiren R. Thakker, which was filed with Supernus’s opening brief. (C.A. 14-6102, Dkt. No. 88-32; C.A. 14-7272, Dkt. No. 74-32.) Exhibits to the Thakker Declaration are referenced as “Thakker Decl. Ex. ____.”
“Thakker Resp.”	The responding declaration of Dr. Thakker, which is filed concurrently herewith. Exhibits to the Thakker Responding Declaration are referenced as “Thakker Resp. Ex. ____.”

I. INTRODUCTION

Plaintiff Supernus Pharmaceuticals, Inc. (“Supernus”) hereby responds to Defendants’ Opening Claim Construction Brief (“Def’s Br.”). (C.A. 14-6102, Dkt. No. 91; C.A. 14-7272, Dkt. No. 77.) For the reasons presented herein and in Supernus’s opening brief, both of which are supported by declarations provided by Stephen R. Byrn, Ph.D. (a pharmaceutical formulation expert) and Dhiren R. Thakker, Ph.D. (a pharmacokinetics expert), Supernus’s constructions should be adopted because they “stay[] true to the claim language and most naturally align[] with the patent’s description of the invention.” *Phillips v. AWH Corp.*, 415 F.3d 1303, 1316 (Fed. Cir. 2005) (en banc) (citation omitted). In contrast, Defendants’ constructions rewrite the claims to add a litany of limitations that are inconsistent with and/or not required by the intrinsic record. Defendants’ constructions should be rejected. “Absent a clear disavowal or contrary definition in the specification or the prosecution history, the patentee is entitled to the full scope of its claim language.” *Home Diagnostics, Inc. v. LifeScan, Inc.*, 381 F.3d 1352, 1358 (Fed. Cir. 2004).

A person of ordinary skill in the art (“POSA”) during the relevant time period would not have construed the claim terms in accordance with Defendants’ constructions. For example, several of Defendants’ proposed constructions ignore the context of the claim terms, which “leads to an overall result that departs significantly from the patented invention.” *On Demand Mach. Corp. v. Ingram Indus., Inc.*, 442 F.3d 1331, 1344 (Fed. Cir. 2006). Additionally, Defendants improperly read limitations into the claims that are plucked from exemplary embodiments. *Liebel-Flarsheim Co. v. Medrad, Inc.*, 358 F.3d 898, 913 (Fed. Cir. 2004) (“[I]t is improper to read limitations from a preferred embodiment described in the specification—even if it is the only embodiment—into the claims absent a clear indication in the intrinsic record that the patentee intended the claims to be so limited.”). Defendants’ incorrect and unduly limited claim constructions should be rejected in their entirety.

II. DEFENDANTS' DEFINITION OF A POSA IS ERRONEOUS

“The inquiry into how a [POSA] understands a claim term provides an objective baseline from which to begin claim interpretation.” *Phillips*, 415 F.3d at 1313. Thus, “[b]efore reviewing the bounds of the claim in light of the specification, the analysis requires attention to the level of skill assigned to a person of ordinary skill in the art.” *AllVoice Computing PLC v. Nuance Commc’ns, Inc.*, 504 F.3d 1236, 1240 (Fed. Cir. 2007).

Supernus’s claim constructions are established from the vantage point of a person having ordinary skill in the pharmaceutical sciences. Drs. Byrn and Thakker opine that a POSA at the time of invention (around 2006) is a person with at least a Bachelor of Science degree in Pharmaceutical Sciences or a related field, approximately 3-5 years of experience in drug delivery technology or a related field, and working knowledge regarding pharmacokinetics (or a person of commensurate education and experience). (Byrn Decl. ¶¶ 18-21; Thakker Decl. ¶¶ 28-32.) Their opinions are correctly based on factors such as the educational level of the inventors, the problems encountered in the art and prior art solutions to those problems, and the educational level of active workers in the field. *See Daiichi Sankyo Co. v. Apotex, Inc.*, 501 F.3d 1254, 1256 (Fed. Cir. 2007).

In contrast, Defendants’ claim constructions improperly depend on a so-called POSA having extraordinary skill: that of an innovative multidisciplinary team. Contrary to the plain meaning of *a person* of *ordinary* skill, Defendants improperly define a POSA as “one or more of, or a *team* including, a Ph.D. or an M.D. . . . [and] *[e]ach* of these individuals would have a working knowledge of one or more of the interdisciplinary fields of pharmaceutical formulation, pharmacokinetics, pharmacodynamics, medicine, and any other related field.” (Defs. Br. at 2-3 (emphasis added).) Defendants’ POSA is erroneous as a matter of law.

Defendants' POSA is based on "what type of person or persons and what type of experiences and knowledge [they should] have *in order to have created that invention*" and "as a consequence" Defendants' POSA is "teams of experts working together." (Thakker Resp. Ex. 13, Mayersohn Tr. 24:11-25 (emphasis added).) Dr. Mayersohn explains that Defendants' POSA is necessarily more than one person. (*Id.* 26:22-27:22.) Thus, Defendants' POSA would be "groups called . . . drug teams. They're flexible. They can include not just people from the sciences but people from economics, for example, and marketing." (*Id.* 27:23-28:18.)

A POSA does not have the viewpoint of "teams of experts working together" (*Id.* 24:11-25) because "[a] person of ordinary skill is also a person of ordinary creativity . . ." *KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398, 420 (2007). Defendants' multidisciplinary "drug teams," which include scientists, medical doctors, economists, and marketing personnel (Thakker Decl. Ex. 13, Mayersohn Tr. 26:6-28:18), are designed to innovate and be creative. This District has "reject[ed] the notion that the 'person' of ordinary skill must possess all of the attributes of a multi-member team." *Otsuka Pharm. Co. v. Sandoz, Inc.*, No. 07-1000, 2010 U.S. Dist. LEXIS 132595, at *27 (D.N.J. Dec. 15, 2010) (Cooper, J.). While a POSA may consult with others, this does not mean that a POSA would be a multidisciplinary team. Indeed, Defendants' expert witness Dr. Park admitted that a suitable POSA for all of the claim terms that he opined on could be a single pharmaceutical formulation scientist. (Byrn Resp. Ex. 20, Park Tr. 23:22-24:22.)

Defendants thus violate the principle that a POSA is "presumed to be one who thinks along the line of conventional wisdom in the art and is not one who undertakes to innovate . . ." *Standard Oil Co. v. Am. Cyanamid Co.*, 774 F.2d 448, 454 (Fed. Cir. 1985). Accordingly, Defendants' arguments and their experts' opinions are presented from the wrong objective baseline for claim interpretation, and should carry little weight.

III. DEFENDANTS SHOULD NOT BE ALLOWED TO CHANGE THEIR CONSTRUCTIONS

During his deposition, Defendants’ expert witness Dr. Mayersohn testified that he changed his constructions of two terms: “a maximum steady state plasma concentration of topiramate” and “the same amount of topiramate administered as an immediate release formulation BID.” (Thakker Resp. Ex. 13, Mayersohn Tr. 33:9-22, 166:3-15.) Defendants’ claim constructions should not be a moving target and Defendants should be held to the constructions that they set forth in the Joint Claim Construction and Prehearing Statement filed pursuant to the Local Patent Rules. (C.A. 14-6102, Dkt. No. 76, at A1-A2; C.A. 14-7272, Dkt. No. 64 (same).) “The [Local Patent Rules] are designed to require parties to crystallize their theories of the case . . . and adhere to those theories once they have been disclosed,” and thus “prevent the ‘shifting sands’ approach to claim construction.” *King Pharm., Inc. v. Sandoz, Inc.*, No. 08-5974, 2010 U.S. Dist. LEXIS 50163, at *10-11 (D.N.J. May 20, 2010) (Arpert, Mag.) (quotations and citations omitted). If Defendants attempt to adopt Dr. Mayersohn’s new constructions, the Court should reject them.

IV. THE COURT SHOULD ADOPT SUPERNUS’S CONSTRUCTIONS

A. “at least two different extended release topiramate-containing components”

Claim Term/Phrase	Supernus’s Construction	Defendants’ Construction
at least two different extended release topiramate-containing components	“at least two extended release topiramate-containing components, <i>wherein each component has its own in vitro rate of drug release</i> ”	“at least two extended release topiramate-containing components <i>having different compositions and release rates for topiramate, within normal variation</i> ”

Defendants agree with Supernus’s construction in that the “‘at least two different extended release topiramate-containing components’ are defined, at least in part, by having their own *in vitro* rate of drug release.” (Defs. Br. at 5.) Although Defendants agree with this part of

Supernus's construction, Defendants argue that the phrase "its own" is allegedly ambiguous because it would allow two components to have the same rate of release. (Defs. Br. at 8.) However, a POSA would understand that a component having "its own" rate of release would have a rate of release that is specific to that component. (Byrn Resp. ¶ 12.) Indeed, Defendants' expert witness Dr. Park acknowledged during his deposition that he understood the phrase "its own" to mean that each component has a "unique rate of release" and that "[u]nique" means different." (Byrn Resp. ¶ 12 (quoting Byrn Resp. Ex. 20, Park Tr. 165:11-17, 166:6-15).)

Thus, the dispute really concerns further claim limitations that Defendants propose, namely that: (1) components "must also have different compositions" and (2) each component would have an undefined and vague "within normal variation" limitation. (Defs. Br. at 5.) Defendants' limitations are inconsistent with and/or unsupported by the intrinsic record, and should not be adopted.

1. Different Compositions Are Not Required for the "at least two different extended release topiramate-containing components"

The specifications demonstrate that two extended release components are "different" when each component has its own in vitro rate of drug release. Despite this, Defendants attempt to import an additional limitation into the claim term that would improperly require that different components also have "different compositions." (Defs. Br. at 5-6.) When arguing for the inclusion of this limitation, Defendants incorrectly reason that "the '580 patent teaches only one way to change the release rate of an extended-release component . . . and that is by changing the composition of that component." (Defs. Br. at 5, 7.) Since Defendants' "different compositions" limitation is allegedly based on how to change the release rate, this demonstrates that the rate of release is *the* differentiating factor for extended release components. Thus, even under Defendants' reasoning, there is no need to add the "different compositions" limitation into the

claims when the parties have agreed to construe the term to require that each component have its own *in vitro* rate of drug release. “The construction that stays true to the claim language and most naturally aligns with the patent’s description of the invention will be, in the end, the correct construction.” *Renishaw PLC v. Marposs Societa’ Per Azioni*, 158 F.3d 1243, 1250 (Fed. Cir. 1998) (internal citation omitted).

a) Defendants’ Argument Relies on an Erroneous Interpretation of the Word “Composition”

Defendants argue that the only way to achieve different rates of release is by changing a component’s composition. (Defs. Br. at 7.) This argument incorrectly characterizes structural changes that occur due to changes in process parameters during manufacture as compositional changes. (Park Decl. ¶ 23.) However, a POSA would interpret a composition as “the ingredients that go into the drug product and must remain in the final product.” (Byrn Resp. ¶ 17 (citing Byrn Resp. Ex. 21, *FDA Guidance for Industry: Drug Product* at 6, lines 238-39); *see also* Byrn Resp. ¶¶ 15-24.) Under a correct interpretation of “composition,” structural changes that occur during manufacturing are not compositional changes. (Byrn Resp. ¶¶ 15, 17, 20-24.) This is confirmed by the specifications’ Tables 2 and 3, which are titled “Hydroxypropyl-beta-cyclodextrin – Topiramate EIR Bead **Compositions**” and “Enhanced Immediate Release Topiramate Bead **Compositions**,” respectively. (Ex. 2, ’580 patent Table 1, Table 2 (emphasis added).) While these tables clearly show the “composition” of these bead populations, the tables do not list either process parameters (such as the curing temperature or method) or solvents used during processing (e.g., water). (Ex. 2, ’580 patent Table 1, Table 2.) By contrast, Table 1, which bears the title “Compositions *and process Parameters* for the extended Release [Topiramate Beads],” distinguishes process parameters from compositions, demonstrating that they mean different things. (Ex. 2, ’580 patent Table 1 (emphasis added).) In addition, none of

the above-referenced tables list the final structure of any of the formulations described therein. (Ex. 2, '580 patent, Table 1, Table 2, Table 3; Byrn Resp. ¶¶ 20-21.) The specifications' express differentiation between compositions and process parameters is consistent with a POSA's understanding that process parameters do not change the composition of a component. "[T]he specification acts as a dictionary when it expressly defines terms used in the claims or when it *defines terms by implication.*" *Phillips*, 415 F.3d at 1321 (emphasis added). Thus, Defendants' arguments rely on an erroneous interpretation of the word "composition."

b) The Specifications Only Require that to Be Different Each Component Must Have Its Own Rate of Release

The specifications demonstrate that "different compositions" are not the only way to change the rate of release. The specifications also teach that the rate of release may be changed by changing process parameters. To sidestep this fact, Defendants use their flawed "composition" interpretation to allege that "changing any one of [the following] variables from one composition to another would result in two coatings with two different compositions":

The release-controlling coating is population-specific in the sense that *the rate of release* of topiramate from every bead population *is controlled by at least one parameter of the release controlling coating, such as* the nature of the coating, coating level, type and concentration of a pore former, *process parameters* and combinations thereof. *Thus, changing* a parameter, such as a pore former concentration, or the *conditions of the curing . . . allows to change the release of topiramate from any given bead population* and to selectively adjust the formulation to the pre-determined release profile.

(Def's Br. at 5-6 (quoting Ex. 2, '580 patent col.7 ll.13-24) (emphasis added).) But under the proper meaning of "composition," changing process parameters does *not* result in a change to the component's composition. (Byrn Resp. ¶ 16-21.) Thus, this excerpt would have demonstrated to a POSA that components with the *same* composition *can* have different release rates by

changing process parameters such as the “conditions of curing.” (Byrn Decl. ¶ 29; Byrn Resp. ¶¶ 15, 20, 26-27; Ex. 2, ’580 patent col.7 ll.13-24.)

Defendants rely on claim 17 of the ’580 patent, but this also does not show that components must have “different compositions” as well as different rates of release. (Defs. Br. at 6-7 (quoting Ex. 2, ’580 patent claim 17).) Claim 17 specifies the proportions of each **component** in that claim’s formulation, and is silent about whether the components differ due to changes in composition or changes in process parameters, such as curing. (Ex. 2, ’580 patent claim 17.) Thus, claim 17 does not support adding Defendants’ proposed limitation.

Defendants further cite the specifications’ Table 1, arguing that it shows compositions “that differ in some way, including . . . the curing method employed.” (Defs. Br. at 7.) While Table 1 includes components with different excipients and/or quantities of excipients, and thus different compositions (and, as a result, different release rates), these are non-limiting examples and do not justify adding a “different compositions” claim limitation. In actuality, Table 1 supports the proper meaning of “composition” by showing that changes in process parameters are distinct from compositional changes. (Ex. 2, ’580 patent Table 1 (entitled “Compositions **and process Parameters** for the extended Release [Topiramate Beads]”) (emphasis added).)

Despite this, Defendants’ assert that the specifications allegedly teach “only one way” to change the rate of release, which is to change the composition of the component. (Defs. Br. at 7.) This assertion is unsound because it relies on Defendants’ incorrect interpretation of the word “composition.” The specifications teach that there are multiple ways to change the rate of release of the component, including process parameters. As discussed above, changes to process parameters, such as curing methods, would **not** result in components with different compositions. Thus, the only required differentiating factor between two components is the rate of release.

Therefore, Defendants’ construction should be rejected because the “different compositions” limitation is not required by the specifications. “Where a specification does not *require* a limitation, that limitation should not be read from the specification into the claims.” *Renishaw*, 158 F.3d at 1249 (emphasis in original, quotation omitted).

Supernus’s construction should be adopted because it is consistent with the specifications’ teaching that components are different when “each component has its own *in vitro* rate of drug release.”

2. “within normal variation” Should Not Be Added to the Claims

Defendants also seek to add the limitation “within normal variation” to the claims, arguing that a POSA would appreciate that “normal” variation occurs during manufacturing and testing, and this limitation allegedly describes what makes components “different.” (Defs. Br. at 8.) But Defendants’ proposed limitation does not make sense because a POSA would not describe something as being *different* “within normal variation.” (Byrn Resp. ¶ 31.) Further, Defendants’ limitation is problematic because the specifications make no mention of “within normal variation” and it is unclear how this limitation is supposed to be applied. A POSA would understand that variation exists and is implied, and thus there is no need to expressly add vague and undefined claim limitations to account for such variation. (See Byrn Resp. ¶ 31.)

Defendants also argue that the prosecution history of one of the patents in suit supports adding this limitation because it discusses alleged prior art references having “uniform” components. (Defs. Br. at 9 (citing C.A. 14-6102, Dkt. No. 78, Peterka Decl. Ex. 7 at 27 (SUPTOP00002239).) However, the applicants were merely distinguishing their invention from prior art references cited by the Examiner, and did not discuss variability within the context of the patents in suit. This does not support Defendants’ argument for adding “within normal variation” to the claims, and it sheds no light on what Defendants’ proposed phrase means.

Therefore, Defendants’ undefined and vague “within normal variation” limitation should be rejected, as it is unsupported by the specifications and prosecution history. “Courts do not rewrite claims; instead, [they] give effect to the terms chosen by the patentee.” *K-2 Corp. v. Salomon S.A.*, 191 F.3d 1356, 1364 (Fed. Cir. 1999).

B. “population[s] of beads”

Claim Term/Phrase	Supernus’s Construction	Defendants’ Construction
population[s] of beads	<p><i>“population[s] of particles, spheres, beads, granules, pellets, particulates or any structural units that may be incorporated into an oral dosage form”</i></p> <p>Construction of “population” is not necessary. The term has its plain and ordinary meaning, e.g., group, collection, or class.</p>	<i>“multiple structural units with the same composition and rate of release, within normal variation”</i>

Defendants’ proposed construction ignores the express definition of “beads” in the specifications, and would add limitations requiring that a “population of beads” have “the same composition and rate of release,” as well as a vague “within normal variation” limitation. (Def. Br. at 10.) Thus, Defendants seek to inject limitations that would mirror those that Defendants proposed for the “at least two different extended release topiramate-containing components” claim term. As a result, Supernus’s arguments against the inclusion of these limitations in Section IV.A *supra* are incorporated by reference.

1. “population[s] of beads” Is a General Term

In contrast to Defendants’ narrow construction, Supernus’s construction of a “population of beads” is consistent with the intrinsic record and a POSA’s understanding. A POSA would recognize that the word “population” needs no construction because the specifications do not assign a special meaning to the word. *Teleflex, Inc. v. Ficosa N. Am. Corp.*, 299 F.3d 1313, 1325 (Fed. Cir. 2002). Therefore, the term should be given its plain and ordinary meaning, e.g.,

group, collection, or class. (Byrn Decl. ¶ 35.) This meaning was confirmed by Defendants’ expert witness Dr. Park, who recognizes that “[p]opulation means a group of beads or a group of people, a group of something.” (Byrn Resp. Ex. 20, Park Tr. 147:15-18.) As discussed below, “population[s] of beads” is used in the claims and specifications to describe multiple aspects of the sustained release formulations, e.g., extended release components, immediate release components, and enhancing agents, which demonstrate that the term should have general applicability. Each use of “population” in the claims and specifications is consistent with the plain and ordinary meaning, and there is nothing in the intrinsic evidence that would indicate to a POSA that the term has some other meaning. (See Byrn Decl. ¶¶ 39-40.) Accordingly, “population” should be given its plain and ordinary meaning. “It is axiomatic that we will not narrow a claim term beyond its plain and ordinary meaning unless there is support for the limitation in the words of the claim, the specification, or the prosecution history.” *3M Innovative Props. Co. v. Tredegar Corp.*, 725 F.3d 1315, 1333 (Fed. Cir. 2013).

The only other portion of the term in need of construction is “beads.” For this, the specifications provide an express definition: “The term ‘beads’ as used herein, includes, without any limitations on the nature and size thereof, any particles, spheres, beads, granules, pellets, particulates or any structural units that may be incorporated into an oral dosage form.” (Ex. 2, ’580 patent col.4 ll.40-43.) Because applicants provided a definition for the term, and there is no indication that they intended to depart from that meaning, the definition in the specifications is the only reasonable construction of the term. See *Phillips*, 415 F.3d at 1316. Thus, Defendants’ modified definition of “beads” should be rejected.

2. Defendants’ Construction Does Not Comport with the Claims and the Specifications

Defendants’ proposed construction ignores surrounding claim language that contains the

term “population[s] of beads.” A POSA would know from the context of the claims what the distinguishing characteristics are for beads in a given population. (Byrn Resp. ¶¶ 35-39.) For example, claim 1 of the ’683 patent recites that the bead population[s] is “coated with *its own release controlling coating* and characterized by *its own rate of release*.” (Ex. 3, ’683 patent claim 1 (emphasis added).) In contrast, the ’191 patent’s claim 1 characterizes “population[s] of beads” as having “a release controlling coating and each having *its own rate of release*.” (Ex. 5, ’191 patent claim 1 (emphasis added); Byrn Resp. ¶ 37.) Thus, requiring Defendants’ “same composition and rate of release” limitation would render certain claim limitations in the ’683 and ’191 patents superfluous. Claims are to be interpreted “in light of the surrounding claim language, such that words in a claim are not rendered superfluous.” *Digital-Vending Servs. Int’l, LLC v. Univ. of Phoenix, Inc.*, 672 F.3d 1270, 1275 (Fed. Cir. 2012). However, with respect to the ’248 and ’989 patents, claim 2 only recites that “the XR component is contained in at least *one* population of beads.” (Ex. 4, ’248 patent claim 2; Ex 6, ’989 patent claim 2 (emphasis added).) Therefore, a POSA would know that the patentees intended that these particular populations can be characterized by *any* similar characteristic. (Byrn Resp. ¶ 38.)

Defendants’ arguments incorrectly rely on the term’s use in conjunction with extended release components, release controlling coatings, and extended release bead populations. (Defs. Br. at 11-12 (citing Ex. 2, ’580 patent col.2 ll.28-34 (extended release populations), col.2 l.59-col.3 l.4 (XR component), col.6 ll.39-45 (extended release component), col.7 ll.13-18 (release controlling coating), col.11 ll.40-51 (extended release component), Fig. 3 (pharmacokinetic data for extended release bead populations), col.4 ll.53-54 (extended release bead populations), col.19 ll.4-26 (extended release populations)).) Defendants’ reasoning is erroneous because “population[s] of beads” is used generally throughout the claims and specifications for “various

aspects of the sustained release formulations.” (Byrn Resp. ¶¶ 40-41, 45.) For example, Defendants ignore that the term is used in the ’683 patent’s claim 17 in the context of an enhancing agent that can be in the form of “a population of beads that are *optionally characterized by a controlled rate of release*.” (Ex. 3, ’683 patent, claim 17 (emphasis added).) Therefore, the surrounding language in the ’683 patent’s claim 17 characterizes the “population of beads.”

The specifications further demonstrate that Defendants’ construction is wrong because not all “population[s] of beads” would have the specific characteristics that Defendants ascribe to them; instead the claims and/or embodiments in the specifications define “common” characteristics for beads of a given population. (Byrn Resp. ¶¶ 36, 39.) For example, the specifications describe that a “*release controlling coating* is population-specific . . . [for] every bead population.” (Ex. 2, ’580 patent col.7 ll.13-16 (emphasis added).) But this does *not* mean that all “population[s] of beads” would necessarily have the same rate of release. (Byrn Decl. ¶ 41.)

Defendants argue that under Supernus’s construction “all beads in a capsule—even if they were both immediate release and extended release—could theoretically constitute a single bead population.” (Def.’s Br. at 12.) However, Defendants failed to appropriately consider the term in the context of surrounding claim language. *Abbott Labs. v. Syntron Bioresearch, Inc.*, 334 F.3d 1343, 1351 (Fed. Cir. 2003) (“The usage of the disputed claim terms in the context of the claims as a whole also informs the proper construction of the terms.”). “The claims clearly specify whether a population of beads is in the immediate release or extended release component.” (Byrn Resp. Decl. ¶ 42.)

Thus, “population[s] of beads” should be construed as “population[s] of particles,

spheres, beads, granules, pellets, particulates or any structural units that may be incorporated into an oral dosage form.”

C. “release controlling coating”

Claim Term/Phrase	Supernus’s Construction	Defendants’ Construction
release controlling coating	<p>“a <i>coating</i> that modifies and controls the release of the active ingredient”</p> <p>Construction of “coating” is not necessary. The term has its plain and ordinary meaning, e.g., a covering.</p>	<p>“a <i>layer of material coated onto a core or other layer</i> that modifies and controls the <i>extended</i> release of the active ingredient”</p>

Supernus’s construction should be adopted because it is based on the express definition of the term “release controlling coating” in the specifications:

[T]he extended release (XR) component is contained in at least one population of beads coated with a *coating that modifies and controls the release of topiramate from the beads (release controlling coating)*.

(Ex. 2, ’580 patent col.6 ll.39-42 (emphasis added).) “[T]he specification acts as a dictionary when it expressly defines terms used in the claims or when it defines terms by implication.” *Phillips*, 415 F.3d at 1321 (quotation omitted). “When a patentee defines a claim term, the patentee’s definition governs” *Honeywell Int’l, Inc. v. Universal Avionics Sys. Corp.*, 493 F.3d 1358, 1361 (Fed. Cir. 2007). The specifications’ express definition of “release controlling coating” should be dispositive for the construction of this term.

Furthermore, the specifications’ definition uses the word “coating,” which would inform a POSA that “coating” is being used in accordance with its plain and ordinary meaning, e.g., “a covering.” (Byrn Decl. ¶ 44 (citing Byrn Decl. Ex. 13, Stedman’s Medical Dictionary at SUPTOP00073839).) “Words of a claim are generally given their ordinary and customary meaning as understood by a person of ordinary skill in the art.” *Innogenetics, N.V. v. Abbott Labs.*, 512 F.3d 1363, 1370 (Fed. Cir. 2008) (quotation omitted).

Defendants add the word “extended” to the specification’s definition of “release controlling coating” but Defendants’ brief did not address this word, suggesting that Defendants assigned no special meaning to it. (Defs. Br. at 18.) The addition of the word “extended” does not make sense in the construction and should be omitted because a coating that extends the release already “modifies and controls the release of the active ingredient.” (Byrn Resp. ¶ 49.) In any event, the parties agree that a release controlling coating “modifies and controls the release of the active ingredient,” and thus the dispute concerns the construction of “coating.” (Defs. Br. at 18.)

1. “coated onto a core or other layer” Improperly Limits the Claims

Defendants seek to add a limitation that the coating must be “coated onto a core or other layer.” (Defs. Br. at 19.) As with “coating material,” Section IV.D *infra*, Defendants’ “coated onto a core or other layer” limitation would wrongly require a particular coating method (due to the “coated onto” recitation). (Byrn Resp. ¶ 51.) Defendants’ argument relies on the specifications’ Example 5 for the proposition that “a ‘coating’ be *applied to a core or other layer*.” (Defs. Br. at 19 (citing Park. Decl. ¶¶ 61-63).) However, Defendants’ limitation is based on a particular method of coating, and would exclude coatings allowed by Example 5’s broad teaching that “*any other suitable apparatus*” may be used to create release controlling coatings. (’580 patent col.18 ll.31-35.) A POSA would know that granulation or microencapsulation techniques are suitable for creating release controlling coatings, and “[d]uring these processes the coating is not actively ‘coated onto’ something; instead these are techniques in which a coating is just formed.” (Byrn Resp. ¶ 51; Byrn Decl. ¶ 54.) Defendants’ “coated onto” requirement is too narrow.

Defendants’ “coated onto a core or other layer” construction would also improperly limit the claims to a component having a “core or other layer.” (Byrn Resp. ¶52.) The specifications

state that “[i]n one embodiment of the invention, the extended release component is contained in at least one population of beads coated with a release controlling coating.” (Ex. 2, ’580 patent col.2 ll.28-30.) By requiring that the release controlling coating is “coated onto a core or other layer,” Defendants improperly narrow the “structures encompassed by the definition of beads.” (Byrn Resp. ¶ 52 (citing Byrn Resp. Ex. 20, Park Tr. 244:10-21).) Defendants’ narrow construction should be rejected. “Absent a clear disavowal or contrary definition in the specification or the prosecution history, the patentee is entitled to the full scope of its claim language.” *Home Diagnostics*, 381 F.3d at 1358.

Defendants’ argument that the specifications disclose embodiments in which a “‘release controlling coating’ is coated onto a core or other layer” is not a proper reason for limiting the claims to that embodiment. (Defs. Br. at 19; *see also* Byrn Resp. ¶ 50.) “[I]t is improper to read limitations from a preferred embodiment described in the specification—even if it is the only embodiment—into the claims absent a clear indication in the intrinsic record that the patentee intended the claims to be so limited.” *Liebel-Flarsheim*, 358 F.3d at 913.

Supernus’s “release controlling coating” construction should be adopted.

D. “coating material”

Claim Term/Phrase	Supernus’s Construction	Defendants’ Construction
coating material	<p>“a material <i>that modifies and controls the release of the active ingredient and is capable of forming a coating</i>”</p> <p>Construction of “coating” is not necessary. The term has its plain and ordinary meaning, e.g., a covering.</p>	<p>“a material <i>coated onto a core or other layer</i>”</p>

The dispute between the parties regarding the construction of “coating material” centers on the following issues with Defendants’ construction: (1) it would require that the “coating

material” *be* a coating when it must only be *capable* of forming a coating; (2) it would improperly narrow the range of potential substrates for the coating material to “a core or other layer”; and (3) it would require a particular method of applying the coating material.

Neither Defendants nor Dr. Park appear to contest that a coating material “modifies and controls the release of the active ingredient,” even though it is not included in their proposed construction. (*See generally* Defs. Br. at 13-18.) A POSA would know that the claimed “coating material” must modify and control release. The claims list specific cellulosic and acrylic polymers for use as the “coating material” and a POSA would know that these materials are used to modify and control release. (Byrn. Decl. ¶¶ 48, 58-60.) Therefore, the requirement that the “coating material” modify and control the release of the active ingredient is correct.

1. A “coating material” Does Not Have to Be a Coating

Defendants reason that the specifications describe that “the core is coated . . . with a solution or dispersion of the release controlling coating material,” and incorrectly conclude that the coating material must necessarily “make up part of a physical coating.” (Defs. Br. at 13.) However, the claims of the ’248 and ’989 patents merely require an “extended release (XR) topiramate-containing component, comprising a *coating material*” (Ex. 4, ’248 patent claim 1; Ex. 6, ’989 patent claim 1.) Thus, “coating material” is recited without a release controlling coating, and therefore the claims allow a “coating material” to “*either* be in the form of a coating *or* be used in another way to control release, such as in certain matrix formulations.” (Byrn Resp. ¶ 61.) A POSA would know “that the ‘coating material’ in these patents is not required to be a coating, but must be capable of forming a coating.” (Byrn Resp. ¶ 61.)

Defendants mistakenly argue that a POSA “would not know” whether an excipient is “capable of forming a coating.” (Defs. Br. at 17-18.) Defendants appear to incorrectly equate “capable” as meaning “must.” Indeed, Defendants argue that for an excipient to be a “coating

material” it must actually be “‘coated onto’ a core or other layer.” (Defs. Br. at 17.) Contrary to Defendants’ argument, a POSA would know what materials would be suitable coating materials based on the specifications and well-known treatises in the art. (Byrn Decl. ¶ 62 (citing Ex. 2, ’580 patent col.7 ll.4-13 (providing an exemplary list of coating materials)); Byrn Resp. ¶ 62 (citing Byrn Decl. Ex. 15, *Handbook of Pharmaceutical Excipients* at SUPTOP00073515-46 (listing materials that are known in the art to be coating agents); Byrn Resp. Ex.17, *National Formulary* at SUPTOP00073576 (providing a list of materials under the heading “coating agent”).) Thus, a POSA would know that the agents listed as “coating materials” are intrinsically capable of forming a coating. (See Byrn Resp. ¶¶ 62-63.)

Defendants also argue various “hypotheticals” that would allegedly affect whether a POSA would “know” whether a material would be capable of forming a coating, stating that the “amount, method of manufacture, and other excipients could affect whether it is possible to form a coating with a particular excipient.” (Defs. Br. at 18.) However, even if *arguendo* such hypotheticals were relevant, Defendants call for a level of precision that is unnecessary in claim construction. “[A] sound claim construction need not always purge every shred of ambiguity.” *Acumed LLC v. Stryker Corp.*, 483 F.3d 800, 806 (Fed. Cir. 2007). The specifications and treatises known in the art, both individually and collectively, provide a POSA with reasonable certainty about what materials are “capable of forming a coating.” (Byrn Resp. ¶ 62.)

Defendants also allege in passing that a coating material can be an “overcoat” or a “drug layering coating” (Defs. Br. at 13), but Defendants do not elaborate on these arguments and they are, in any event, wrong. In fact, Defendants’ expert Dr. Park relies on such concepts to improperly assert that a “coating material” must be a coating. (Park Decl. ¶ 52; Byrn Resp. ¶¶ 56-60.) A POSA would have known that neither of these concepts are relevant to the

construction of “coating material,” since the coating material is used in the claims solely in the context of an extended release component. (*See* Byrn Resp. ¶¶ 56-60.)

2. A “coating material” Need Not Be “coated onto a core or other layer”

Defendants’ construction wrongly limits a “coating material” such that it must always be “coated onto a core or other layer.” Defendants’ argument is analogous to saying that because paint may be coated onto a wall, all paint must necessarily be coated onto a wall—which would limit the term “paint” to exclude, for example, paint that is in a bucket or paint coating a ceiling. Such reasoning is illogical. Defendants’ proposed construction is also inconsistent with the specifications’ teachings because the “coated onto” limitation would restrict the claims to certain methods for applying the coating material. However, as discussed in Section IV.C, *supra*, Defendants rely on Example 5, which expressly teaches that “any other suitable apparatus” can be utilized to create a coating. (Park Decl. ¶ 28; Byrn Resp. ¶ 51; Ex. 2, ’580 patent col.18 ll.31-35.) Since Defendants’ construction excludes other techniques known to a POSA for modifying and controlling the release of an active ingredient (Byrn Resp. ¶ 51), it should be rejected because it improperly narrows the scope of the claims. *Home Diagnostics*, 381 F.3d at 1358 (“Absent a clear disavowal or contrary definition in the specification or the prosecution history, the patentee is entitled to the full scope of its claim language.”).

Additionally, Defendants’ proposed limitation requiring a “core or other layer” is inconsistent with the language of the claims. The claim language “provide[s] substantial guidance as to the meaning of particular claim terms.” *Phillips*, 415 F.3d at 1314; *see also Abbott*, 334 F.3d at 1351 (“The usage of the disputed claim terms in the context of the claims as a whole also informs the proper construction of the terms.”). The construction improperly limits claim 1 of the ’248 and ’989 patents, which recite, *inter alia*, “an extended release (XR) topiramate-containing **component**, comprising a coating material” (Ex. 4, ’248 patent

claim 1 (emphasis added); Ex. 6, '989 patent claim 1 (emphasis added).) With no basis to do so, Defendants' construction would limit such claims for a "component" to a specific component having a "core or other layer." This is narrower than the specification's definition of beads: "any particles, spheres, beads, granules, pellets, particulates, or any structural units." (Byrn Resp. ¶ 52 (quoting Ex. 2, '580 patent col.4 ll.40-43).) Defendants' expert witness Dr. Park apparently agrees that "core or other layer" is narrower than "beads." (Byrn Resp. ¶ 52 (citing Ex. 2, '580 patent col.4 ll.40-43; Byrn Resp. Ex. 20, Park Tr. 244:10-21).)

Contrary to Defendants' assertion, the prosecution history does not support their construction. (Defs. Br. at 16.) Defendants misleadingly cite a portion of the prosecution history in which the applicants were arguing that it is improper to combine one prior art reference ("Park") with two other references ("Venkatesh" and "Chen"). (C.A. 14-6102, Dkt. No. 78, Peterka Decl. Ex. 7 at 30 (SUPTOP00002242).) The applicants were not distinguishing the claims from the references (Defs. Br. at 16); instead the applicants argued that "as a matter of law, the combination of Park with Venkatesh and Chen is improper" because to do so "would change the principle of operation *of the prior art* invention being modified." (*Id.* (quotation omitted, emphasis added).) The prosecution history does not mention the "release controlling coating" and "coating material" claim terms. Since this citation does not address any of the claim limitations of the patents in suit, there was no disclaimer of claim scope. *Cordis Corp. v. Boston Sci. Corp.*, 561 F.3d 1319, 1329 (Fed. Cir. 2009) ("A disclaimer must be 'clear and unmistakable,' and unclear prosecution history cannot be used to limit claims.").

Defendants also argue that dependent claim 10 of both the '248 and '989 patents would support requiring a "release controlling coating" in claim 1 of the '248 and '989 patents because the independent claims recite a "coating material" and the dependent claims recite a "release

controlling coating.” (Defs. Br. at 14.) This was a drafting error, as the dependent claims should have recited “the coating material.” The patentees have petitioned the U.S. Patent and Trademark Office to correct these claims. (Byrn Resp. Ex. 23, ’248 Patent Request for Certificate of Correction at SUPTOP00191922, 24; Byrn Resp. Ex. 24, ’989 Patent Request for Certificate of Correction at SUPTOP0191936, 38.) Furthermore, these drafting errors do not impact Supernus’s construction of the term “coating material.” (*See* Byrn Resp. ¶ 64.)

Defendants’ construction of “coating material” is contrary to the words of the claims and the specifications, and should be discarded. Supernus’s construction should be adopted because it aligns with the intrinsic evidence and comports with the understanding of a POSA.

E. “a maximum steady state plasma concentration (C_{max}) of topiramate”

Claim Term/Phrase	Supernus’s Construction	Defendants’ Construction	Defendants’ Expert Witness Dr. Mayersohn’s Newly Proposed Construction
a maximum steady state plasma concentration (C _{max}) of topiramate	“a maximum plasma concentration (C _{max}) of topiramate <i>reached</i> during a dosing interval while at steady state”	“a maximum plasma <i>drug</i> concentration (C _{max}) of topiramate <i>that is the calculated mean value based on values obtained from a group of subjects tested</i> during a dosing interval while at steady state”	“a maximum plasma <i>drug</i> concentration (C _{max}) of topiramate <i>that is the calculated mean value based on values obtained from a group of subjects tested</i> during a dosing interval at steady state <i>while using a crossover design study</i> ”

Defendants propound an unreasonable interpretation of the definition of “steady state” and allege that there is no dispute about the main difference between the parties’ constructions. (Defs. Br. at 20.) Defendants’ construction improperly adds a claim limitation that C_{max} would have to be calculated “based on values obtained from a group of subjects *tested during* a dosing interval while at steady state.” Instead of addressing this issue, Defendants allege that the dispute concerns the recitation “the calculated mean value based on values obtained from a group of subjects tested.” (*Id.*) Defendants ignore that the specific *placement* of this recitation in their

proposed construction would require using clinical study designs that dose subjects to steady state before measuring plasma concentrations. Additionally, Defendants' expert witness Dr. Mayersohn changed his construction during his deposition, which would further limit the claims to require crossover study designs. (Thakker Resp. Ex. 13, Mayersohn Tr. 33:14-22.) Supernus objects to this new construction (*see* Section III, *supra*), but addresses it here in an abundance of caution. Defendants' and Dr. Mayersohn's claim constructions should be cast aside.

Supernus's construction should be adopted because it stays true to the claim language and is aligned with the specifications. (Thakker Decl. ¶¶ 48-59.) Both the intrinsic record and extrinsic evidence establish that "a maximum steady state plasma concentration (C_{max}) of topiramate" should be construed as "a maximum plasma concentration (C_{max}) of topiramate reached during a dosing interval while at steady state."

1. "steady state" Does Not Require Repeated Administration in a Patient or Subject to Determine Pharmacokinetic Values

Despite Defendants' statements to the contrary, Supernus does not "agree" that the definition of "steady state" would "require[]" repeated administration of topiramate "in a patient or subject" to determine steady state values. (Defs. Br. at 20.) Defendants' interpretation is unreasonable. The "steady state" definition simply describes an equilibrium *state*, and it does not describe or imply any particular method of determining steady state values. (Thakker Resp. ¶¶ 15-16, 21.) The specifications are consistent with this definition, as they describe that steady state values can be determined after repeated administration in patients or subjects (Example 6 part (b)) *and* that steady state values can be simulated by applying the superposition principle after a single administration (Example 6 part (a)). (Thakker Resp. ¶¶ 17-18, 27-30.) In addition to the specifications' express teachings, a POSA would know that steady state pharmacokinetic parameters can be simulated using the superposition principle, and that such a method is

commonly employed to evaluate steady state pharmacokinetics. (Thakker Resp. ¶¶ 19-20, 22-26.) Thus, Defendants’ interpretation of “steady state” is plainly wrong.

2. The Placement of “the calculated mean value based on values obtained from a group of subjects tested” Limitation in Defendants’ Construction Excludes Single Dose Clinical Study Designs

Defendants’ arguments concerning “the calculated mean value based on values obtained from a group of subjects tested” is a distraction. (Defs. Br. at 20-22.) There is no reason to add this recitation into the claims (at any place in the construction) because a POSA would consider this to be implied for pharmacokinetic parameters (Cmax and AUC) in the patents in suit. (*See* Thakker Resp. ¶¶ 40-41.) In the context of the patents in suit, it is understood that pharmacokinetic results from clinical studies are “based on values obtained from a group of subjects” that are tested. (*Id.* ¶¶ 38-40.) In other words, to determine pharmacokinetic parameters, it is understood that at some point subjects must be tested to determine concentrations of drug in the blood. (*Id.* ¶ 40.) It is also implied in the context of the patents that a mean value will be calculated. (*Id.*) As the specifications explain, the calculated mean value is used to account for “interpatient variability [among individual subjects] in the many parameters affecting drug absorption, distribution, metabolism, and excretion.” (Ex. 2, ’580 patent col.4 ll.22-29; *see also* Thakker Resp. ¶ 34.) That Defendants did not seek to include “the calculated mean value” in their AUC term construction (*see* Section IV.F *infra*) further demonstrates that it is unnecessary to add such a limitation here. Thus, “the calculated mean value based on values obtained from a group of subjects tested” recitation should not be added.

More problematic is Defendants’ **placement** of this recitation in the Cmax construction, which rewrites the claims to require that steady state Cmax must be “based on values obtained from a group of subjects **tested during** a dosing interval while at steady state.” (Thakker Resp. ¶¶ 37, 39; Thakker Decl. ¶¶ 51, 57.) As written, this limitation requires administration of

repeated doses to subjects (until steady state is reached) before measuring plasma concentrations. Defendants' limitation would restrict the claim scope to exclude steady state Cmax values that are calculated by applying the superposition principle to data obtained from a single dose study. (Thakker Resp. ¶¶ 12-13, 37; Thakker Decl. ¶¶ 51, 57.) "Absent a clear disavowal or contrary definition in the specification or the prosecution history, the patentee is entitled to the full scope of its claim language." *Home Diagnostics*, 381 F.3d at 1358. There is no disavowal here.

The superposition principle is expressly used in the specifications' Example 6 part (a). (Thakker Resp. ¶ 18.) The superposition principle was used to simulate steady state pharmacokinetic results based on data that was obtained from subjects who were administered a single dose of topiramate. (*Id.*; Ex. 2, '580 patent col.18 l.59-col.19 l.50; *see* Thakker Decl. ¶¶ 37, 42, 54.) The superposition principle allows the plasma concentration levels after repeated administrations to be calculated based on single dose data, so that subjects do not have to be tested during a dosing interval while at steady state. (Thakker Resp. ¶¶ 18-20.) Thus, subjects in part (a) were **not** tested during a dosing interval while at steady state. (Thakker Resp. ¶¶ 16-20.) Defendants' construction would exclude using the superposition principle to model steady state values. This violates the canon that a "person of ordinary skill in the art is deemed to read the claim term not only in the context of the particular claim in which the disputed term appears, but in the context of the entire patent, including the specification." *Phillips*, 415 F.3d at 1313.

Even without the express teaching provided in Example 6, a POSA would not limit the scope of the claims as Defendants' propose. As mentioned above, the superposition principle is commonly used to determine steady state pharmacokinetic values (Cmax and AUC) because it does not require administering doses repeatedly until steady state is reached, but instead allows

steady state values to be calculated based on a single dose. (Thakker Resp. ¶ 19; Thakker Decl. ¶ 37.) Thus, a POSA viewing the claims would not add Defendants’ proposed limitation.

3. The Claims Are Not Limited to Crossover Study Designs

Defendants’ expert witness Dr. Mayersohn stated during his deposition that he was changing his construction of the Cmax term to add a further limitation: “while using a crossover design study.” (Thakker Resp. Ex. 13, Mayersohn Tr. 33:14-22.) As discussed in Section III, *supra*, Defendants should not be allowed to change their proposed constructions. In any event, this new limitation proposed by Dr. Mayersohn should not be written into the claims because neither the claim language nor the specifications require using a crossover study design.

Dr. Mayersohn argues that a crossover study should be added to the claims because Example 6 used crossover studies. As described in more detail in Section IV.F.1, *infra*, this is not a valid reason to limit the scope of the claims to exclude other types of valid study designs, including parallel studies. Therefore, Dr. Mayersohn’s new construction should not be adopted.

F. “a relative steady state AUC”

Claim Term/Phrase	Supernus’s Construction	Defendants’ Construction
a relative steady state AUC	“an area under the plasma concentration-time curve (AUC) of topiramate from the formulation administered once-daily while at steady state in relation to the AUC of topiramate from an immediate release formulation administered <i>daily in two divided doses</i> while at steady state”	“an area under the plasma concentration-time curve (AUC) of topiramate from the formulation administered once-daily while at steady state in relation to the AUC of topiramate from an immediate release formulation administered <i>twice a day in two equal doses</i> while at steady state <i>based on values obtained from a group of subjects tested by a crossover study</i> ”

Defendants’ construction improperly narrows the scope of the claims by requiring:

(1) that the relative AUC specifically be “based on values obtained from a group of subjects tested by a crossover study,” instead of any other clinical study design that a POSA could use,

and (2) that the immediate release formulation must necessarily be administered “in two equal doses,” instead of two divided doses as described in the specifications. (Defs. Br. at 22-23; Thakker Decl. ¶¶ 67-68; Thakker Resp. ¶¶ 31-36, 42-45.) Defendants’ attempt to add new and uncalled-for limitations into the claims should be rejected because “the resulting claim interpretation must, in the end, accord with the words chosen by the patentee to stake out the boundary of the claimed property.” *Renishaw*, 158 F.3d at 1248.

1. The Claims Are Not Limited to Crossover Study Designs

Nothing in the claim language or specifications requires using a crossover study. (*See also* Section IV.G *infra*.) Defendants argue that this limitation should be incorporated into the claims because the specifications’ Example 6 happened to use a crossover study and no other examples were given. It is improper to read limitations from an example into the claims, even if it is the only example, absent a clear indication in the intrinsic record that the patentee intended the claims to be so limited. *See Liebel-Flarsheim*, 358 F.3d at 913. There is **no** indication that the claim language should be so limited. The specifications do not require—or even state a preference for—a crossover study over any other kind of clinical study that could be used. (Thakker Resp. ¶¶ 31-34.) “Where a specification does not **require** a limitation, that limitation should not be read from the specification into the claims.” *Renishaw*, 158 F.3d at 1249 (emphasis in original, quotation omitted).

A POSA would know that other study designs, such as parallel studies, can be used and that such studies may even be preferable for drugs with a relatively long half-life such as topiramate. (Thakker Resp. ¶¶ 35-36.) Defendants did not argue (nor could they) that a POSA would have to use a crossover study. (Defs. Br. at 24 (arguing that a crossover study is allegedly the “proper method” and is a “standard manner” of conducting studies).) Indeed, references cited by Defendants’ expert witness Dr. Mayersohn confirm that parallel studies are used in the

art, and have some advantages over crossover designs. (Mayersohn Decl. Ex. D, Bolton at SUPTOP00074150 (explaining that “[t]here are also some problems associated with crossover designs. A crossover study may take longer to complete than a parallel study because of the extra testing period. . . . Another disadvantage of the crossover design is that missing data pose a more serious problem than in the parallel design. . . . Finally, the administration of crossover designs in terms of management and patient compliance is somewhat more difficult than that of parallel studies.”); Mayersohn Decl. Ex. F, *FDA Guidance* at 19 (explaining that for a “pharmacokinetic study involving an oral product with a long half-life drug . . . [i]f the crossover study is problematic, a [bioequivalence] study with a parallel design can be used.”).) “[A]n alternative means of accomplishing the claimed result weighs against a claim construction that would exclude that alternative.” *3M Innovative Props.*, 725 F.3d at 1331. A POSA would not limit the claims to only crossover studies. (Thakker Decl. ¶¶ 39, 68; Thakker Resp. ¶¶ 31-36.)

2. Administration “twice a day in two equal doses” Is Not Required

Defendants’ proposed “twice a day in two equal doses” limitation should be rejected. The specifications expressly describe administering immediate release formulations in “two divided doses.” (*See* Ex. 2, ’580 patent col.1 ll.45-46, col.6 ll.2-8.) While such doses could be equal, they are *not necessarily* equal. (Thakker Decl. ¶¶ 67-68; Thakker Resp. ¶¶ 43-45.) For example, as Dr. Thakker explains, if only 50 mg tablets of an immediate release product are available and 25 mg of the immediate release product is to be administered twice a day (“BID”), a POSA would know to physically divide the 50 mg tablet into two halves. (Thakker Resp. ¶ 44.) Therefore, the two divided doses (i.e., each half of the tablet) would have a similar dosage amount, but likely would not be exactly equal.

Thus, “a relative steady state AUC” should be construed as “an area under the plasma concentration-time curve (AUC) of topiramate from the formulation administered once-daily

while at steady state in relation to the AUC of topiramate from an immediate release formulation administered daily in two divided doses while at steady state.”

G. “the same amount of topiramate administered as an immediate release formulation BID”

Claim Term/Phrase	Supernus’s Construction	Defendants’ Construction	Defendants’ Expert Witness Dr. Mayersohn’s Newly Proposed Construction
the same amount of topiramate administered as an immediate release formulation BID	“the equivalent amount of topiramate administered daily as an immediate release formulation given twice a day”	“the equivalent amount of topiramate administered daily as an immediate release formulation given twice a day <i>in the same subjects</i> ”	“the equivalent amount of topiramate administered daily as an immediate release formulation given twice a day <i>in equal amounts in the same subjects</i> ”

The plain language of this term concerns the *amount* of topiramate to be administered.

To this extent, the parties agree because both parties’ constructions recite “the equivalent amount of topiramate administered daily as an immediate release formulation given twice a day.”

Defendants would construe this term to further require that the equivalent amount be administered “‘*in the same subjects*’ as opposed to different individuals, or different groups of individuals.” (Defs. Br. at 25.) Defendants do not explain why a POSA would assume that the “amount” of a drug to be administered would limit the subjects that should receive the drug. Additionally, Defendants’ expert witness Dr. Mayersohn changed his construction to inject an “in equal amounts” limitation, which is not called for by the claim term. (Thakker Resp. Ex. 13, Mayersohn Tr. 166:3-15.) Supernus objects (*see* Section III, *supra*), but addresses the new construction in an abundance of caution. Defendants’ limitations should be rejected because “[c]ourts do not rewrite claims; instead, [they] give effect to the terms chosen by the patentee.” *K-2*, 191 F.3d at 1364 (citing *Texas Instruments Inc. v. ITC*, 988 F.2d 1165, 1171 (Fed. Cir. 1993) (explaining that “courts can neither broaden nor narrow claims” (quotation omitted))).

There is no basis to add Defendants' proposed "in the same subjects" limitation, which is another attempt by Defendants to limit the claim scope to require the use of crossover studies. (Defs. Br. at 25; *see also* Section IV.F.1 *supra*.) Defendants argue that this limitation would be warranted because the specifications recognize that there is intersubject variability in blood plasma drug concentrations. (Defs. Br. at 25.) Therefore, Defendants argue, a POSA would assume that a crossover study should be used when comparing pharmacokinetic parameters because a crossover study happened to be used in Example 6 and reported in Tables 5 and 6. (Defs. Br. at 25-26 (citing Ex. 2, '580 patent col.4 ll.22-25, Example 6, Tables 5 and 6).) But Defendants' argument inexplicably ignores the specifications' express teaching that the use of mean values is employed to account for intersubject variability: "[f]or this reason [i.e., intersubject variability], unless otherwise indicated, when a drug plasma concentration is listed, the value listed is the calculated mean value based on values obtained from a group[] of subjects tested." (Ex. 2, '580 patent col.4 ll.22-29.) Moreover, as explained in Section IV.F.1, *supra*, while Example 6 happened to use a crossover study, the specifications do not require using a crossover study. Furthermore, the specifications do **not** state that crossover studies should be used because of intersubject variability, or even state a preference for crossover studies. (Thakker Resp. ¶ 34.) Indeed, a POSA would know that other types of studies, such as parallel studies, can be designed to account for intersubject variability. (Thakker Resp. ¶ 35.) The difference between reading the claim in light of the specification and importing a limitation turns on whether the patent specification expresses the "clear intention to limit the claim scope." *Liebel-Flarsheim*, 358 F.3d at 906. The specifications do not show any intent to limit the claim scope to require crossover studies.

Finally, Dr. Mayersohn's change to his construction to add an "in equal amounts" limitation should be rejected. As explained in Sections III and IV.F.2, *supra*, the change is untimely and, further, "in equal amounts" is not required by the specifications.

Therefore, Supernus's construction should be adopted because the intrinsic and extrinsic evidence demonstrate that "the same amount of topiramate administered as an immediate release formulation BID" should be construed as "the equivalent amount of topiramate administered daily as an immediate release formulation given twice a day."

V. CONCLUSION

For the foregoing reasons, the Court should adopt Supernus's constructions in their entirety. Supernus's constructions stay true to the claim language, are aligned with the patents' description of the invention, and are consistent with the understandings of a POSA.

In stark contrast, Defendants' constructions are wrong as a matter of fact and law. Defendants' constructions would improperly limit the scope of the claims by excluding embodiments described in the specifications, importing limitations from the specifications into the claims, and rewriting the claims to add limitations that are not required by or even mentioned in the specifications. Defendants also propound constructions that are contrary to the specifications. Further, Defendants' arguments and their expert witnesses' opinions should be given little weight because they are not presented from the perspective of a person having ordinary skill in the art. In sum, Defendants' erroneous constructions should be rejected.

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